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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,184	11/25/2003	Jeffrey O. Phillips	03207556	7922

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EXAMINER	
CHANG, CELIA C	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding..

Office Action Summary	Application No.	Applicant(s)	
	10/722,184	PHILLIPS, JEFFREY O.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *151-157,159-170 and 174-210* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *151-157,159-170 and 174-210* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of group I, omerpazole composition in the reply filed on Feb. 9, 2006 is acknowledged.

Claims 158, 171-173, 211-218 are withdrawn from consideration. Claims 151-157, 159-170, 174-210 are pending.

2. Claims 151-157, 159-170, 174-210 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is well recognized in the art that blood concentration of a drug after an oral dose is a dose dependent process. The specification provided blood concentration measurements using single 40 mg omeprazole in 20 mEq sodium bicarbonate. Such results can support the serum profile for a single 40 mg omeprazole dosing but not the instantly claimed scope wherein a 0.05mEq-5mEq buffer per mg omeprazole "composition" is able to achieve a 0.1 μg/ml within 30 minutes of dosing. There is no evidence in the record that a composition meeting the ratio requirement without at least a therapeutically effective dose of omeprazole can achieve such a blood level. In addition, there is no evidence in the record that such blood level can be obtained when the drug to buffering agent ratio varied beyond the single 40 mg omeprazole-20 mg sodium bicarbonate composition. Please note, the agents as listed in claim 161 all have different pH, ionic strength, buffering capacity, there is no evidence that all such broad range of basic compounds can form buffer (see Bull p.103). Nor was there any support that the wide varieties of basic agent of claim 161 would all function in analogous manner in providing serum absorption as the 40 mg omerprazole/20 mg sodium bicarbonate coadministation.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 151-157, 159-170, 174-210 are rejected under 35 U.S.C. 102(b) as being anticipated by Carroll et al. , McCullough US 5,447,918, Depui et al. WO 97/25066, JP 05-255088 supplemented with Horowitz (all cited on 1449).

Carrol, McCullogh (col. 15, example 12), Depue (p. 27, lines 5-6) or Jp'088 (p. 5 tables 0018) disclosed composition anticipated the claims with the dosage and base combination. The limitation of serum level within 30 min is the innate nature of such composition as evidenced by Horotwitz (see page 792, col. 2, wherein after the oral administration of 90 mg omeprazole with 300 ml 160 mmol/l sodium bicarbonate, corresponding to 0.53 meq/mg omeprazole i.e. the claimed range, the medium time to reach the peak plasma concentration C mas-11.3±1.4 μm/l or 3.8 μg/ml is 30 min). Therefore, anticipation was found. Please note that before tableting, a powder mixture/composition was in possession by the prior art.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 151-157, 159-170, 174-210 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carroll et al. , McCullough US 5,447,918, Depui et al. WO 97/25066, JP 05-255088 in view of Carroll et al., Borody US 5,443,826 and Horowitz.

Determination of the scope and content of the prior art (MPEP §2141.01)

Carroll et al., McCullough, Depie or JP'088 disclosed the claimed composition as delineated supra for the achievement of the required serum level within 30 min as supplemented by the evidence of Horowitz.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art composition is that the prior art composition are in prepared dosage form while the instant claims required the elements to the composition in a powder for suspension. Carroll et al. taught that a capsule or pellet/tablet can be open or crushed to be suspended. Borody et al. taught that composition for treatment of gastrointestinal disorder ordinarily can be in powder form which is readily reconstituted with omeprazole for naso-duodenal infusion. Horotwitz taught (see page 792, col. 2) that after the oral administration of 90 mg omeprazole with 300 ml 160 mmol/l sodium bicarbonate, corresponding to 0.53 meq/mg omeprazole i.e. the claimed range, the medium time to reach the peak plasma concentration of 0.1μg/ml (C_{max} =11.3±1.4 μm/l or 3.8 μg/ml) is 30 min.

Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

On having ordinary skill in the art is deemed to be aware of all the pertinent art in the field. The above references placed the variation of compositions in the possession of artisan in the field. Furthermore, the field informed artisan to employ pelleted or unit dosage forms being crushed for coadministration with other antiacid in suspension or keep the composition in a powder form by lyophilization or pulverization. In addition, Horotwitz et al. evidenced that the reaching of plasma concentration of 0.1μg/ml is the innate nature of Omeprazole coadministed with bicarbonate. Therefore, the skill, the suggestion and the expected outcome of the claims are well delineated in the field, thus, in possession by artisan. One skilled in the art would be motivated either to keep the composition in powder without tableting or pelleting, or pulverize a tablet or pellet to be suspended in a solution for naso-duodenal infusion.

5. Claims 151-157, 159-170, 174-210 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the issued claims of U.S. Patent No. 6,699,885; 6,645,988; 6,489,346; 5,840,737. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims differ from the issued claims only by the innate nature of the composition in plasma concentration after 30 min. Such innate nature is a well documented nature for such product by Horowitz as explained supra.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
April 26, 2006

Celia Chang
Primary Examiner
Art Unit 1625